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Public and Expert Voices in the Legal Regulation of Technology

Patrick Bishop and Stuart Macdonald

Introduction

The law in isolation is seldom, if ever, an adequate regulatory device. As Black contends in her exposition of decentred regulation: "... governments do not [...] have a monopoly on regulation [...] regulation is occurring within and between other social actors" (Black, 2001, p103). Indeed, the use of alternative instruments to achieve regulatory goals has proliferated in recent times; Thaler and Sunstein's influential "nudge" theory (Thaler and Sunstein, 2009) is one obvious manifestation of the preference on the part of policy makers for non-regulatory solutions to social problems. But whilst innovation in the design of policy instruments is laudable, there remains a place for more traditional command and control regulation. As Macrory notes, "it remains equally important to ensure that the qualities of transparency, accountability, and enforceability inherent in the more formal legal structures are not lost" (Macrory, 2001, p647).

The focus of this chapter is the legal regulation of technology. In one sense, to distinguish between the regulation of technology and the regulation of other things is a false dichotomy. Technology does not exist in a vacuum and any regulation of it is essentially concerned with limiting and controlling the uses that may be made of technology by humans. In short, any form of legal regulation is concerned with behavioural control and regulating technology is no exception. In another sense, however, the targeted activity of any regulatory scheme will influence both its creation and eventual operation and here the highly specialist and complex nature of technology – and its associated risks – are certainly capable of raising distinct challenges. The chapter examines three technological areas which have been subjected to legal regulation: human fertilisation and embryology; the manufacture and distribution of chemicals; and, the disposal of hazardous waste. Whilst these activities, and the regimes which regulate them, are quite different, they do share two basic common features. First, the activities themselves are necessary and/or socially beneficial. And, second, the activities also have the potential to cause considerable harm – at both the individual and societal level – if left unregulated.

Efforts to regulate activities like these face various challenges. For a start, efforts at legal regulation of technology struggle to keep pace with scientific advances. This has been characterised as a race between the 'hare' of technology against the 'tortoise' of law (Stokes, 2012, p93). It is also apparent that despite an initial period free of regulation, new high-tech products and processes are eventually caught by a bespoke regulatory net or, failing that, fall within existing regulatory regimes with broad and overlapping remits (Friedman, 2001).

A further challenge, which is the focus of this chapter, is managing the frequent tension between public and expert opinion. Technological advancement is a key ingredient of the 'new modernity' conceptualised by Beck: "in social science's understanding of modernity, the plough, the steam locomotive and the microchip are visible indicators of a much deeper process, which comprises and reshapes the entire social structure" (Beck, 1992, p.51). This reshaped social structure is "... increasingly preoccupied with the future (and also with safety), which generates the notion of risk" (Giddens, 1999, p.3). Any legal regime tasked with the regulation of risk is necessarily complex and multifarious and involves the input of science and expertise (to provide assessments of risk) and the public at large in order to gauge society's response to particular dangers and their likelihood. These

drivers of regulatory design and approach will often (if not inevitably) exist in mutual tension. This chapter will explore this tension via an analysis of three distinct regulatory regimes. These regimes have been chosen as they each have different structures and legislative underpinnings: UK domestic law (Human Fertilisation and Embryology Act 1990), EU law (REACH Regulation 2006) and international law (Basel Convention 1989). Before turning to these, the chapter begins by examining the role public participation plays in legal regulation in general, and the tension between this objective and considerations of resource and expertise.

Public and expert voices in regulatory design: the theory

The literature on principles of ‘good regulation’ reveals a high level of consensus regarding the importance of public participation (Baldwin, Cave and Lodge, 2012; Regulating Better, 2004; Mandelkern Group on Better Regulation, 2001; Regulatory Performance Indicators, 1999). In environmental matters the importance of public participation has been fully recognised at the international level (Aarhus, 1998). The rationale for enhanced participatory rights is rooted in democratic concerns, particularly in the context of non-majoritarian regulatory bodies. As Abbot and Lee have noted:

The political nature of environmental decisions, together with their frequent delegation to unelected experts, requires public participation to enhance the procedural legitimacy of decisions, since electoral legitimacy is weak. (Abbot and Lee, 2003, p.84)

In addition to justifications based on democracy, there is also ample support for the view that decisions and policies made as a result of a participatory process produce higher quality results than would be the case absent any public input (Abbot and Lee, 2003, p.83; McGarity, 1990, p.112). The basis of such an argument is that public participation is able to broaden the regulator’s lens beyond the purely technical aspects of the particular regulatory regime, which in turn will allow the regulator to view issues from different perspectives (McGarity, 1990, p.112). Theoretical support for this may be gleaned from the social science research methodology known as ‘triangulation’, which involves the “use of more than one approach to the investigation of a research question in order to enhance confidence in the ensuing findings” (Bryman, 2004, p.1143). It is also important to note that, despite the often technical nature of regulatory regimes, expertise alone is incapable of providing a complete solution to most regulatory challenges. As McGarity has opined: “... many, if not most, important health and environmental questions are in fact not resolvable by the experts. The available information and the state of the scientific art is often so poor that the experts can at best hazard highly uncertain educated guesses.” (McGarity, 1990, p.105). Even where experts are able to provide a reasonably accurate assessment of risks this in no way provides an answer to the vexed societal question of how much risk is acceptable. In this regard the public “can provide useful information on matters such as public fears and values” (Abbot and Lee, 2003, p.82). Finally, involvement in the decision making process provides interested parties with a better understanding of how decisions are made which in turn has the potential to reduce the scope for judicial review (McGarity, 1990, p.112).

In spite of these benefits, there are two sets of concerns about public participation. The first are practical, and focus on operational efficiency. In a world of finite resources, it is inevitable that cost minimisation and efficiency concerns will permeate the design and operation of any regulatory regime. As discussed below, this is certainly the case with the three areas of regulation considered in this chapter. In such a context, it is generally accepted that public participation will have considerable resource implications, both in terms of money and time (Abbot and Lee, 2003, p.87; McGarity, 1990, p.112). Moreover, an over-emphasis on participation as a condition precedent of regulatory action has

the potential to damage a regulator's ability to respond to issues in a timely manner: "more participation might lead to less effective decision making and eventually to stagnation in the regulatory system" (Baldwin, Cave and Lodge, 2012, p.29).

By contrast, the second set of concerns focuses not on resources but on the ability of the public to engage in what are often technical, even esoteric debates. As Eden has noted:

[O]ne of the circumstances that can militate against this admirable objective is where discussions are dominated by 'experts' of one sort or another. This precludes wide public involvement by defining the discussions as the exclusive preserve of 'experts' (Eden, 1996, p.183).

This view is shared by a number of commentators (Baldwin, Cave and Lodge, 2012, p.29; Lee and Abbot, 2003, p.84; McGarity, 1990, p.113). However, whilst members of the public "have not always had the power or the confidence of their own 'expertise' to raise their criticisms forcefully" (Eden, 1996, p.191), Baldwin, Cave and Lodge point out that in Beck's 'risk society' there is a "new political dialogue built on the death of deference to those claiming special expertise" (Baldwin, Cave and Lodge, 2012, p.30). Moreover, any attempt to preclude public debate on the basis that only 'experts' are capable of reaching an appropriate decision undermines the democratic foundations on which public participation is based and the legitimacy of any subsequent decisions.

Having outlined this tension between public participation on the one hand and operational efficiency and expertise on the other, the chapter will now examine how these considerations have been managed in three contrasting regulatory regimes specific to differing technological contexts.

Human Fertilisation and Embryology

Following the birth in the UK in 1978 of the first child conceived through *in vitro* fertilisation (IVF), a Committee of Inquiry was established in 1982 under the chairmanship of Dame Mary Warnock to consider the social, ethical and legal implications of the advances in human fertilisation and embryology and to make recommendations on the policies and safeguards that should be applied. When it was published in 1984, one of the Warnock report's principal recommendations was the creation of an independent regulatory authority (Department of Health & Social Security, 1984). This body would have both executive and advisory functions, and would include not only representation from the scientific and medical communities but also lay members in order to ensure public confidence and participation (ibid, para 13.4).

Following the Warnock report's recommendations, the Human Fertilisation and Embryology Act 1990 (the 1990 Act) established the Human Fertilisation and Embryology Authority (HFEA). The HFEA's functions include, first, licensing and monitoring: clinics that carry out IVF and donor insemination treatment; centres that carry out human embryo research; and, the storage of gametes and embryos. Activities which infringe this regulatory framework, such as unlicensed treatment, constitute a criminal offence (1990 Act, s 41). Second, the HFEA issues a Code of Practice and maintains formal registers of information about donors, fertility treatments and children born as a result of these treatments. And, third, the HFEA publicises its role and provides advice and

information to patients, donors and clinics. The HFEA currently has 12 members.¹ These members have a range of expertise, including medicine, law, religion and philosophy. To encourage an independent view, the HFEA requires that at least half of its members (including the Chair and Deputy) are not doctors or scientists involved in human embryo research or fertility treatment.

Whilst stating that the 1990 Act had worked well – enabling science and medicine to flourish within agreed parameters and promoting public confidence – the Government decided in 2005 that a review of the law and regulation in this area was “timely and desirable” in the light of technological developments in assisted reproduction and changing public attitudes (Department of Health, 2006, paras 1.2-1.3). When it reported in 2006, one of the review’s key outcomes was to reiterate the Government’s commitment (first announced in 2004) to creating the Regulatory Authority for Tissue and Embryos (RATE). The intention was that RATE would replace the HFEA and the Human Tissue Authority (HTA) with a single regulator with responsibilities across the range of human tissues, cells and blood (ibid, para 1.4). It was suggested that this merger would prevent overlapping regulation and ensure the application of “common principles and standards” across these “closely linked areas” (ibid, para 3.2). The Government’s proposal was for the creation of a RATE board, charged with taking a more strategic role, supported by (non-executive) Expert Advisory Panels (EAPs) to ensure that expertise would be available in all areas of activity within its remit (ibid, paras. 3.10-3.16).

Following the publication of a draft Bill in May 2007, a Joint Parliamentary Scrutiny Committee was established. The Joint Committee’s report, in July 2007, found “overwhelming and convincing” evidence against establishing RATE (Joint Committee on the Human Tissue and Embryos (Draft) Bill, 2007, para 92). The Committee stated that, whilst there were some synergies between the work of the HFEA and HTA (ibid, para 60) and a merger offered some potential efficiencies and cost savings (ibid, para 61), there were also significant risks. The broad remit of RATE could result in a loss of both specialist expertise (ibid, para 76) and HFEA’s national and international reputation (ibid, para 73). There are also significant differences between the work of the HFEA and HTA (ibid, para 69), and public confidence could be affected by the loss of a dedicated authority for embryos – which are widely regarded as meriting a special status (ibid, para 65). Moreover, RATE’s proposed structure could result in it being little more than a rubberstamping authority, with the EAPs functioning effectively as the HFEA and the HTA (ibid, para 85), and it would be possible to achieve some efficiencies without a formal merger (ibid, para 82). Following the Joint Committee’s report the Government decided not to proceed with RATE, and focussed instead on how the two authorities could work together to streamline their operations (Secretary of State for Health, 2007, para 17).

The Joint Committee’s report also expressed concern that the draft Bill lacked “the explicit underpinning ethical framework which in 1990 was provided by the Warnock Report” (Joint Committee on the Human Tissue and Embryos (Draft) Bill, 2007, para 44). This was due, in part, to the fact that the Act being created was an amending statute. In other words:

Nowhere was a blank piece of paper offered for reform, in a way that allowed for a thorough and fundamental rethinking of the kind of regulation which might best suit this area or the

¹ In January 2013 the HFEA reduced the size of its board from 19 members to 12. It reports that this “smaller board size is now widely recognised to be more effective” (Human Fertilisation and Embryology Authority, 2014, p16). It has also gradually reduced its staff complement, from 86 in 2010/11 to 64 by the end of the 2013/14 financial year (ibid).

ethical principles which should underpin it. Rather the architects of reform worked outwards from the provisions already in place, making the key question not ‘what model of law do we want?’ but rather ‘what needs to be changed?’ (McCandless and Sheldon, 2010, p180)

So whilst the resulting Human Fertilisation and Embryology Act 2008 (the 2008 Act) made some significant changes – including: permitting the creation and use (under licence) of animal-human hybrid embryos for research purposes; prohibiting the selection of the sex of offspring for non-medical reasons only (thereby allowing the screening of embryos to select a saviour sibling); removing the requirement to consider the future child’s “need for a father” when deciding whether a woman should be accepted for treatment services; and, providing for the first time that two women may be recognised as a child’s legal parents from the moment of birth – it also represented a missed opportunity in other important respects. For example, the way parenthood is framed within the legislation continues to prioritise married couples (even though this is at odds with other developments in family law), assume a two parent model and regard parents as occupying complementary yet different roles (hence a lesbian co-mother is not a mother but a female parent) (McCandless and Sheldon, 2010). The 2008 Act also made only minimal changes to the law and regulation of surrogacy. In particular, there remains a distinction between full surrogacy (to which the 1990 Act applies²) and partial surrogacy (where there is a “regulatory vacuum” (Horsey and Sheldon, 2012, p73)). This distinction is difficult to justify and in the latter case “leaves individuals dependent on the efforts of ‘well meaning amateurs’, who are prevented from charging the fees that would otherwise allow them to professionalise their services” (ibid, p87).³

In addition to an appropriate ethical framework, the Joint Committee emphasised the importance of an “appropriate, consistent and workable regulatory architecture”. This entails “finding the right balance between flexibility and legal certainty” (Joint Committee on the Human Tissue and Embryos (Draft) Bill, 2007, para 49). Claiming that the Government had favoured legal certainty and, as a result, “been over-prescriptive in many areas in an attempt to provide for every eventuality”,⁴ the Joint Committee argued for “a more flexible approach within clearly defined parameters” (ibid, para 55). This principle of “devolved regulation” would, it suggested, provide regulators and clinicians with greater freedom of action and future-proof the legislation as technology continued to develop (ibid, para 56). In keeping with this more “permissive” approach, the Committee also recommended that the HFEA be given a statutory power to define areas of exemption from the regulatory remit where appropriate (ibid, para 105). These recommendations were not accepted by the Government, however, who asserted that “such a framework would introduce a lack of accountability” (ibid, para 8), “would cause uncertainty about the scope of regulation” (ibid, para 11), and “would be confusing and open up the HFEA to increased litigation and judicial review” (ibid, para 11).

² Although as Blyth (2012) notes the fact that this “became a vehicle for exercising some measure of regulation over surrogacy was largely serendipitous” (p309).

³ Some of the difficulties are illustrated by *Re T (a child) (surrogacy: residence order)* [2011] EWHC 33 (Fam). See further Alghrani, 2012; Vijay, 2014.

⁴ One possible example is the express prohibition of using reproductive technologies to ensure the birth of a child with a particular disability (2008 Act, s 14(4)). For an argument for a more flexible approach to this issue, see Taylor, 2010.

The future of HFEA was examined again following the 2010 General Election. As part of its programme for Government the Coalition Government made a commitment to cut the number of health arm's length bodies and reduce bureaucracy significantly. The Department of Health accordingly stated that the HFEA and HTA would be retained temporarily as separate arm's length bodies, with a view to transferring their functions to other bodies by 2015 (Department of Health, 2010). After a consultation found that the majority of respondents did not favour this proposal (Department of Health, 2013a), an independent review into the operation of the two bodies was set up, led by Justin McCracken. The McCracken report found that "There is almost universal praise for the Human Fertilisation and Embryology Act, and recognition that it is still fit for purpose" (McCracken, 2013, para 4.5). The report emphasised that the work of the HFEA and HTA is, by and large, separate, and that the "specialist expertise in the regulators and their understanding of the science underpinning commercial developments in the field were cited as critical, and important to preserve" (ibid, para 4.2). This specialist expertise was also found to be key to maintaining "[p]ublic confidence in the sensitive areas regulated by the HFEA" (ibid, para 4.1). Since a merger offered only "relatively modest additional cost savings" and "Much of the potential benefit of merger can be achieved by merging the two Finance and Resource groups while retaining the separate statutory entities with their respective Chairs, Chief Executives, and Boards" (ibid, para 4.18), the report recommended retaining the HFEA as a separate body. This was accepted by the Government (Department of Health, 2013b), and the recommendations have since been implemented (Human Fertilisation and Embryology Authority, 2014).

In her comparison of the UK's and US's approaches to human embryonic stem cell research, Schechter (2010) states that:

To some, it may seem counterintuitive that the United Kingdom, with its stringent regulatory and licensing standards, would be more effective at encouraging research than the United States and its relatively lax, unrestrictive approach. However, considering the state of the science in this field, the level of uncertainty created by the lack of uniformity and oversight, and the benefits of comprehensive regulation, the federal government needs to play an active role in this area if it wants to see real, competitive progress (p629)

The regulatory oversight provided by HFEA has, she argues, allowed the UK to develop a "consistent and progressive" approach (ibid, p620). By contrast, in her discussion of whether the Netherlands should create a similar regulatory body to the HFEA, Zeegers (2014) has suggested that such a model can result in "bad politics" (p13). Using hybrid embryos as a case study, and pointing in particular to the fact those who opposed the creation of hybrid embryos on moral and ethical grounds were not only "misled by the idea that the creation of true hybrid embryos would not be at issue" but also had their beliefs "turned into an argument for facilitating an even wider range of human animal forms of embryo" (ibid, p27), she argues that the regulatory mechanism resulted in "a neutralization and downplaying instead of a real reconciliation of differences in moral views" (ibid, p26). This resonates with a comment in the McCracken report which, whilst generally very positive, did assert that there is "a fairly widespread sense that the HFEA needs to do more to properly take into account stakeholder views and to be seen to do so" (McCracken, 2013, para 4.5).

The manufacture and distribution of chemicals

The ubiquitous use of chemicals (and chemical technologies) undoubtedly provides innumerable benefits to society but can also cause considerable damage to human health and/or the environment. As Stokes and Vaughan posit: "...chemicals can hold concurrent and fundamentally opposed

positions in our legal and social consciousness: being both savior and sinner in the same instant” (Stokes and Vaughan, 2013, p.435). The regulation of chemicals poses challenges of immense complexity, in at least three different ways. First, the central mechanism of chemicals control in the EU, the REACH Regulation (Regulation 1907/2006/EC (OJ L396/1 2006)) - an acronym for the Registration, Evaluation, Authorisation and Restriction of Chemicals - is not designed with a single objective in mind (see generally Vaughan, 2015). Early EU action in this area (Council Directive 67/548/EEC) was motivated primarily by single market aims and the desirability of correcting information asymmetries. In a modern context, the objectives of EU chemicals regulation have been extended to explicitly include the protection of human health and the environment, facilitate market integration and to promote innovation in the chemicals sector (Heyvaert, 2007, p.201). Second, chemicals regulation is essentially concerned with the identification and management of risk as informed by regulatory science (Funtowicz et al, 2000). The limitations of science conducted primarily to inform policy are well-documented. Regulatory science is often characterised by extrapolation: from high to low dosage levels, from animals to humans, from short-term to long-term exposure (Jones, 2007). As noted earlier, even where science is able to provide an accurate assessment of risk this in no way provides an answer to the difficult societal question of how much risk is acceptable – but this is a question that any regulatory regime must address. Finally, any chemicals regulatory scheme is faced with considerable challenges of scale. While the exact number of chemicals on the market is unknown, the REACH Regulation is only applicable to chemicals manufactured or imported in the EU at or over one tonne per annum. The European Chemicals Agency expects at least 30,000 existing chemicals to be registered in this category by 2018 (European Chemicals Agency, 2015). These complexities have unquestionably shaped the substance and form of EU chemicals policy.

REACH is a legislative instrument of immense complexity, density and length. The text of the consolidated version is over 130,000 words in length, accompanied by over a million words of guidance issued by the European Chemicals Agency (ECHA). Thus, only the briefest of summaries is possible here!

The title “REACH” encapsulates the full range of regulatory mechanisms utilised by the regime. A staged approach is adopted commencing with the registration of chemicals, followed by their evaluation and then, where applicable (depending on the outcome of evaluation), their authorisation and possible restriction. The first of these steps – the registration process – is arguably the most significant. Here a ‘no data, no market’ approach is employed. Manufacturers or importers of chemicals must apply for registration, a process which involves the submission of a technical data file supplying, inter alia, the identity of the chemical, its intended use, physical properties and toxicological/ecotoxicological information (art.12(1)). This process represents a reversal of the traditional approach to market regulation for the purposes of environmental protection:

Whereby most environmental regulation operates as a limit on market activity, ‘you can do what you like but not x’. Such laws dictate what particular kinds of behavior are not allowed. In contrast, registration is operating as a precondition to market activity (Fisher, 2008, p.553).

A further noteworthy feature of the registration requirement is that the duty to conduct the necessary risk assessments is delegated to private actors.

Following registration, a substantive evaluation of the registered information is required for all chemicals manufactured or imported in quantities exceeding 100 tonnes or (irrespective of volume) where the data supplied raises concerns about health and/or environmental impacts (art.44(2)). An EU-wide rolling action plan has been established, where a substance targeted for evaluation is allocated to a Member State to act as rapporteur. When concerns are confirmed, evaluation may

trigger further measures, such as the inclusion of the chemical on the list of substances subject to authorisation, or the drafting of risk reduction measures. All chemicals designated as 'Substances of Very High Concern' (SVHC) require authorisation before they can be marketed or used within the EU (art.56). Firms are required to offer proof that the risks created by the SVHC are either 'adequately controlled' or there is a 'socio-economic need for their continued use, while no viable alternative currently exists' (title VII). This authorisation process therefore encompasses the principle of substitution, namely, if safer alternatives exist the SVHC must be phased out. The Commission is ultimately responsible for authorisation, which must be granted if the risks are shown to be adequately controlled. If this proves to be impossible, the Commission may still grant authorisation taking into account the severity of the risk and the viability of alternative substances. In reaching its decision the Commission has to follow the advisory comitology procedure under scrutiny (art.64(8)). While a detailed examination of this procedure is beyond the scope of this chapter, a central feature is the significant influence of the European Parliament, which can oppose a Commission authorisation proposal with a simple majority. Finally, for those substances which pose unacceptable risks to human health and the environment, restrictions represent the ultimate safety net. Restrictions take many forms, from a total ban to not being permitted to supply a substance to the general public.

The REACH Regulation is a multi-faceted legislative instrument which adopts a variety of different approaches. As well as mechanisms which may be termed 'command and control' (authorisation, restriction) it also relies on essentially market-based instruments (registration, provision of information). Similarly, the system is both centralised (integral role for the Commission, ECHA, etc.) and devolved (obligation on private actors to provide technical data). Of especial relevance to this chapter is the registration and provision of information requirement.

From one perspective, the obligation placed on private actors to register technical data relating to chemical risks is a practical necessity given the sheer volume of substances manufactured and marketed within the EU. It may be seen as a workload sharing mechanism (Fleurke and Somesen, 2011, p.372). However, the requirement also has a substantive rationale. In an unregulated world, producers and manufacturers would have few incentives to provide information about chemical risks. As Wagner has noted:

Actors who create externalities are best suited to access and produce information on the nature of the harms that their activities cause, but they also stand to lose from providing such information (Wagner, 2004, p.1648).

Thus, by requiring the provision of information as condition of entry to the EU chemicals market, the 'no data, no market' principle may be seen as a form of regulated self-regulation. In addition to an entry requirement, the registration requirement has other functions. First, the risk assessment which forms the basis of the registered information might highlight risks which can trigger evaluation, authorisation and restriction measures. And, second, the provision of data is essentially a market-based mechanism capable of providing information to all participants in the supply chain including the end consumers of products. Where risks are deemed unacceptable to the market, the responding purchasing (in)activity will send a clear signal to those further up the supply chain (Case, 2005, p.383). This in turn might advance the goals of innovation, protection of health and protection of the environment by providing an incentive to manufacturers to produce substances which pose less significant risks. This objective is supported by the maintenance of a publicly accessible database administered by the ECHA.

In one sense it is difficult to disagree with the assertion that all participants in a market should be granted access to fullest body of information possible; indeed information asymmetry is seen as a significant cause of market failure. However, the desirability of the approach adopted by REACH has

not been accepted axiomatically. Durodie, for example, has referred to the ‘social cost of fear reduction’ and questioned the need for the risk assessment obligation for existing substances:

Accordingly, while one might usually favour seeking to obtain the greatest possible amount of evidence in deliberating upon matters, there would appear to be a clear need in this instance to maintain some sense of perspective and priorities. This is especially so as most of the chemicals now being required to be tested have been in use for a quarter-century or more and have effectively acquired billions of hours of exposure data through consumption or use (Durodie, 2003, p.390).

In a similar, more hyperbolic vein, the REACH Regulation has been described as “economic suicide by a massive self-administered regulatory overdose” (Logomasini and Miller, 2005, p.13). In addition to such concerns based on the fear of over-regulation, doubts have been expressed about the effectiveness of informational regulation, based on the public’s ability to engage fully with a highly technical area:

Data produced in accordance with registration requirements and housed on ECHA’s website are dense and technical and beyond the means of comprehension of the vast majority of EU citizens. At the same time, users of chemicals have been provided with Safety Data Sheets (which detail risks and risk mitigation measures) by chemical manufacturers and importers that are now, thanks to REACH, up to 1,000 pages long per substance and, as a consequence, often meaningless. The quality of the data produced to date has also been poor, a fact recognised by both ECHA and the Commission. Put simply, more information is not always better information (Stokes and Vaughan, 2013, p.427).

One possible counter to such arguments is the existence of environmental pressure groups and other NGOs, who might possess the necessary expertise and therefore perform a watch-dog role capable of pressurising the chemicals sector (Case, 2005, pp.420-423). Even eight to nine years after the enactment of REACH, the slow transmission rate of market information means it is still too early to discern the efficacy of its registration and information requirements.

The disposal of hazardous waste

In June 1987 – following the discovery, in Africa and other parts of the developing world, of illicit dumps of imported hazardous waste – the United Nations Environment Programme (UNEP) established a working group tasked with elaborating a global convention on the control of transboundary movements of such wastes. But whilst there was a growing recognition of the threat posed by hazardous waste to both human health and the environment, and of the difficulties developing countries have in managing waste (Shearer, 1993), the application of more exacting environmental standards in the developed world had meant that “dumping in the less regulated (or unregulated) developing world [had become] a cheaper and more commercially attractive option” (Morrow, 2010, p.219). Unsurprisingly, then, the debates on the new convention were “politicized, arduous and emotionally charged” (Kummer, 1998, p.227). The resultant Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal was adopted on 22 March 1989, and entered into force on 5 May 1992. To date, it has been ratified by 183 countries (Basel Convention, 2015).

In keeping with its stated aim of reducing the transboundary movement of hazardous waste, the Basel Convention imposes a general, non-legally enforceable,⁵ obligation on States to reduce the generation of hazardous waste to a minimum (Article 4(2)(a)) and to ensure that adequate disposal facilities are available within their jurisdiction for the environmentally sound management (ESM) of hazardous waste (Article 4(2)(b)). The Convention also prohibits the export of hazardous waste to Antarctica, to states that are not party to the Basel Convention, and to states that have banned the import of hazardous waste (Article 4). But the Convention stops short of imposing a total ban on exporting such waste. First, Article 4(9)(a) permits the transboundary movement of hazardous waste if the exporting state lacks “the technical capacity and the necessary facilities, capacity or suitable disposal sites in order to dispose of the wastes in question in an environmentally sound and efficient manner”. Waste may therefore be moved to another state in which its disposal will be managed in an environmentally sound manner. Second, Article 4(9)(b) allows wastes to be exported if they “are required as a raw material for recycling or recovery industries in the State of import” (Article 4(9)(b)). This recognises the fact that waste has a “dual character” (Morrow, 2010, p228), as both pollutant and tradable resource.

The regulatory framework for exporting hazardous waste is based on the principle of Prior Informed Consent (PIC). Article 6(1) requires the authorities of the exporting state to notify the authorities of the prospective states of import and transit of the proposed transboundary movement. The movement may only proceed once all states concerned have given their written consent, including confirmation of the existence of a contract between the exporter and the disposer specifying environmentally sound management of the waste in question (Article 6(3)(b)). Importantly, Article 4(10) stipulates that the state that generated the hazardous waste cannot transfer its obligation to manage the waste in an environmentally sound manner to a transit or import state. This notion of cradle-to-grave liability underpins the duty (found in Article 8) to re-import wastes when their movement cannot be completed in accordance with the terms of the contract, and is also significant in cases where it is difficult to determine fault for an improper disposal. The principal weakness of the PIC mechanism, however, is that it relies on self-verification by states and so requires good faith from all concerned. This has a number of flaws. First, the exporting country may fail to verify that the facility accepting the waste in the importing country can manage it in an environmentally sound manner. This is compounded by the fact that the technical guidelines generated under the Convention are not mandatory, and so “a country attempting to self-verify a facility cannot assume that the destination country is observing the Basel ESM guidelines for a specific waste” (Gutierrez, 2014, p407). Second, the exception for wastes which are required for recycling or recovery in the importing state may be exploited, creating a “recycling loophole” (Gutierrez, 2014, p407). Data suggests that since the Convention entered into force a significant proportion of waste that was destined for final disposal has headed instead for recycling or further use (Gutierrez, 2014). It has even been suggested that “exporters often misrepresent the nature of the wastes, misleading importing nations into consenting” (Onzivu, 2013, p636). And, third, there is the possibility of corruption in the importing country:

⁵ It is important to note that the reduction obligation is expressed in such qualified terms (and with no specific target) that it would make it extremely difficult to factually establish a breach; as such, it seems that the obligation to reduce the generation of hazardous waste represents a symbolic provision rather than a legally enforceable obligation.

Another weakness in the PIC procedure is its omission to account for the susceptibility of country consents to be obtained from corrupt local officials. It also ignores the economic motivation of poor countries to accept these types of wastes for either the value or money that the waste can contribute to the local economy. (Gutierrez, 2014, p407)

In cases involving illegal traffic in hazardous waste, the Convention envisages a core role for criminal liability (Article 4(3)) alongside liability under civil law (Article 4(4)). But whilst a protocol on liability was adopted in 1999, this is not yet in force as it lacks the required number of ratifications. Since there is no liability regime under the Convention, parties must rely on domestic law for redress. Yet in many (developing) countries there is weak multi-sectoral co-ordination of waste management and monitoring of waste law (Onzivu, 2013). The Basel Convention does have some financial mechanisms, including the Basel Convention Trust Fund to Assist Developing Countries and other Countries in Need of Technical Assistance (the BD fund). But this too is problematic, since it is based on voluntary contributions by signatories who tend to accrue significant arrears (Morrow, 2010). Further mechanisms for promoting implementation and compliance include: regional training centres (BCRCs), which provide technical assistance for parties to safely manage hazardous and other wastes (Article 14(1)); a requirement to submit an annual report to the Conference of the Parties (Article 13(3)); and, a duty to participate in hazardous waste audits conducted by the Secretariat (Article 10(2)(b)). The effectiveness of these has also been questioned, with BCRCs lacking sufficient funding and capacity and states failing to submit national reports to the Secretariat (Onzivu, 2013).

During the negotiations on the Basel Convention African countries, supported by other developing countries and environmental NGOs, had pushed for a total worldwide ban on transboundary movements of hazardous wastes, claiming that this was necessary to protect poorer regions from becoming the dumping grounds of the wealthy North (Kummer, 1998). When the Basel Convention was formally adopted the Organization of African Unity (OAU) expressed its disappointment at the lack of a total ban, stating that the restrictions imposed by the Convention “could be circumvented because of the lack of competent administrators and administrative agencies” (Shearer, 1993, p151). As a result, the OAU subsequently adopted the Bamako Convention, which creates a total ban on the importation of all hazardous wastes into Africa and limits the transfer of such wastes within Africa – thereby making the “difficult choice for most African countries placed between the double negative alternatives of ‘poverty or poison’” (Eze, 2007, p229). Importantly, the Bamako ban includes recycling and reclamation activities. This limits African industry to the use of traditional raw materials in production methods and, it has been suggested, underestimates the growing importance of waste as a valuable resource which can create green business opportunities and jobs (Kummer Peiry, 2013). In fact, it has been argued that the “ambitious provisions” of the Bamako Convention are “so stringent” that they “threaten its enforceability” (Shearer, 1993, pp174-5). Pointing to “The complete absence of reported activities by the Bamako Secretariat and the Conference of the Parties” and the *Probo Koala* incident in the Ivory Coast in 2006, Eze concludes that “the lofty ideals of the Convention might be lost to the impossibility of compliance with its provisions” (2007, pp228-9). On the other hand, the Bamako Convention has an important symbolic effect, sending the message that African nations are not dumping grounds for hazardous wastes generated in other countries. It has also acted as a catalyst for other, similar, regional agreements, as well as the Basel Ban Amendment. The latter measure provides for a ban on the transfer of hazardous wastes for final disposal from Organisation for Economic Cooperation and Development (OECD) to non-OECD countries. Although it has not yet been ratified by enough countries to bring it into force, the Ban Amendment has been ratified by, and so has legal effect in, the EU.

Commentators have warned of the dangers of treaty congestion (Morrow, 2010; Onzivu, 2013). Treaty congestion further complicates this already-complex area. For a start, different treaties may have different ambits: for example, the Bamako Convention encompasses sea disposal of hazardous wastes, whereas the Basel Convention expressly excludes this from its scope (Article 4(12)). The two Conventions also define hazardous waste differently (Eze, 2007, pp216-7). Second, even if there is an attempt to delineate the scope of different treaties, the application of this in individual cases may be contested. In the *Probo Koala* incident, for example, one of the key issues was whether the sludge created by the floating refinery constituted hazardous waste or whether it was in fact slops, which are expressly excluded from the Basel Convention (Article 1(4)) and instead fall under the International Convention for the Prevention of Pollution from Ships 1973 (the MARPOL Convention) (Morrow, 2010). Similarly, there has been debate as to whether end-of-life ships constitute hazardous waste, so that the Basel Convention applies to the shipbreaking industry (Karim, 2010). Third, the previous two points are compounded by the fact that the definition of waste depends on the view of its generator. This subjectivity allows “the waste disposer effectively to opt for obeying the regime that imposes the least demanding standards in the context of the disposal of hazardous waste in the developing world” (Morrow, 2010, p229). Moreover, the Convention’s definition of ESM as “taking all practicable steps to ensure that hazardous wastes or other wastes are managed in a manner which will protect human health and the environment against the adverse effects which may result from such wastes” (Article 2(8)) is vague and open to different interpretations depending on one’s interests (Gutierrez, 2014). Such complexity and lack of clarity generates uncertainty.

Public and expert voices in regulatory design in practice

No legal or regulatory system can operate without significant discretionary power. As Bradley and Ewing observe, “If it is contrary to the rule of law that discretionary authority should be given to government departments or public officers, then the rule of law applies to no modern constitution” (2003, p94). Given the inevitability of discretion in every legal system, proponents of what has been dubbed the “extravagant version of the rule of law” (Davis, 1971, pp28-33) seek to eliminate as much discretion as possible. Beyond this they urge the need to “bring such discretion as is reluctantly determined to be necessary within the ‘legal umbrella’ by regulating it by means of general rules and standards and by subjecting its exercise to legal scrutiny” (Lacey, 1992, p372). One of the difficulties with this, however, is that it mistakenly assumes that there is a neat dichotomy between rules and discretion. In fact, the distinction between the two is far more uncertain (Galligan, 1986; Hawkins, 1992). As the examples examined in this chapter illustrate, discretion is heavily implicated in the interpretation of regulatory norms and the application of them to technological processes and practices. Assessments under the REACH regime of whether the risks posed by a Substance of Very High Concern have been adequately controlled, whether there is a socio-economic need for the substance’s continued use and whether a viable alternative exists all involve discretionary judgement, as do decisions as to whether a state lacks the technical capacity and necessary facilities to dispose of hazardous waste in an environmentally sound and efficient manner and decisions as to whether a proposed research project involving embryos is necessary or desirable for the purpose of promoting advances in the treatment of infertility, increase knowledge about the causes of congenital disease or miscarriages, or develop more effective contraceptive techniques (1990 Act, Schedule 2, section 3).

It is also apparent that, within each of the technological contexts examined in this chapter, certain viewpoints are prioritised in the exercise of this discretionary judgement. Perhaps most starkly, under the Basel Convention the view of the waste generator is relevant to the application of the definition of hazardous waste. Hence in the *Probo Koala* incident the company (Trafigura) that chartered the

floating refinery was able to contend that the 528 tons of sludge deposited around the city of Abidjan was in fact slops (governed by the MARPOL Convention), not hazardous waste (governed by the Basel Convention). And whilst a stated objective of both the HFEA and REACH frameworks is to promote public participation, the extent to which this objective is realised is open to question. As noted above, it has been suggested that the HFEA model results in bad politics. Whilst membership of the Authority includes a range of disciplinary perspectives, and there is a cap on the number of members who are doctors and scientists involved in human embryo research or fertility treatment, it is also the case that previous reviews have emphasised the important role the Authority plays in facilitating further innovation and development and that three of the seven current lay members are women who have previously received IVF treatment (Human Fertilisation and Embryology Authority, 2015). Indeed, the McCracken report stated that the HFEA needs to do more to properly take into account stakeholder views (McCracken, 2013). Meanwhile, REACH's registration process is, amongst other things, intended to operate as a mechanism for providing information to end consumers of products. But as has been pointed out, not only is the information provided normally dense and highly technical, meaning it is incomprehensible to the vast majority of members of the public, it is also often based on poor quality data and can be hundreds of pages in length. In reality, then, the opportunity for end consumers to contribute, via the market, to decisions about acceptable levels of risk is limited.

As well as the role played by discretion and the prioritisation of certain viewpoints, a third recurring theme across the regimes for regulating technology examined here, as in many other contexts, is the importance of resource considerations. In spite of the high regard in which the HFEA is held, twice in less than a decade there have been proposals to merge it with the HTA for the sake of efficiency savings. Resource constraints also greatly hinder the operation of the Basel Convention, most obviously in the lack of third party verification of the PIC process. There is also a *de facto* lack of third party verification of the REACH registration process; with over 30,000 existing chemicals expected to be registered by 2018, the sheer magnitude of the regulatory task – and the level of resource that would be required to police this – means that the oversight of the ECHA is necessarily limited. Both regimes are thus, in effect, forms of “regulated self-regulation” (Crawford, 2003). This means, first, that the regulatory frameworks might be circumvented by those prepared to act in bad faith. As explained previously, the Basel Convention's PIC process has been criticised on the grounds that exporting states might deceive importing states and vice versa. It is also possible that exporting and importing states might act in collusion. This is exacerbated by the fact that the protocol on liability is not yet in force and by the difficulties in taking action under domestic law. And whilst REACH requires each member state to maintain an enforcement regime which provides “effective, proportionate and dissuasive” penalties for non-compliance (Health and Safety Executive, 2015), this will prove little disincentive to those who wish to act in bad faith and who, as a result of the limited degree of oversight, perceive the likelihood of being caught to be low (von Hirsch et al, 1999). As well as bad faith, an additional possibility is a formalistic or minimalistic attitude towards compliance with the regulatory requirements. The frequent resort to the Basel Convention's “recycling loophole”, for example, is at odds with the spirit of the Convention and the ESM principle. Similarly, during the REACH registration process manufacturers or importers of chemicals might submit a file that provides the required data but does so in a partial or selective manner. Meanwhile those who act in good faith and seek to comply fully with the regulatory requirements risk being rendered uncompetitive – both in comparison to those who do not comply fully and those who sit outside the regulatory regime in question. For example, concern has been expressed that the Bamako Convention will increase the cost of doing business in Africa and act as a disincentive to foreign investors (Eze, 2007), whilst to comply fully with the burdensome requirements of the REACH regime may result in

“paralysis by analysis” (Jones, 2007, p.356) – not only leaving European businesses less competitive than those from other parts of the globe but also potentially reducing social utility by slowing product development.

Conclusion

This chapter began by outlining why public participation has been deemed a principle of good regulation, and explaining the tension between this objective and considerations of resource and expertise. It then examined this tension in the context of three specific regulatory regimes. The chapter has shown that in each of these regimes certain viewpoints are prioritised in the exercise of the discretionary decision-making that the regimes inevitably contain. What is striking about this is that, in each context, the viewpoint that is prioritised emanates from within the regulated industry: whether it is IVF doctors, researchers or patients; waste generators; or, chemical manufacturers and importers. Moreover, resource constraints mean that the latter two are effectively left to self-regulate, whilst public confidence in the HFEA is consistently attributed to its expert status. This not only raises questions about the extent to which these regulatory regimes do in fact exert effective control over the activities in question, but also whether the limited scope for public participation diminishes the legitimacy of these decision-making processes.

By way of conclusion, it is worth returning to the false dichotomy between rules and discretion noted earlier. As Hawkins observes, to suggest that “discretion in the real world may be constrained only by legal rules” is to “overlook the fact that it is also shaped by political, economic, social and organizational forces outside the legal structure” (Hawkins, 1992, p38). At a time when regulators resort all too readily to the enactment of new laws as a response to societal challenges (Ashworth, 2000), it is important to appreciate not only the limitations of legal regulation of technological processes and practices, but also to recognize – and seek to harness – the potential role of these extra-legal constraints.

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